JUL 27 2011

K110703

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BD

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Summary Preparation: March 11, 2011

1. **Submitted By:**

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2. **Device Name:**

Trade Name:	BD AutoShield™ Duo Pen Needle
Common Names:	Insulin Pen Needle
Classification Name:	Needle, Hypodermic, Single Lumen
Classification:	Class II, 21 CFR 880.5570 FMI

3. **Predicate Device:**

BD AutoShield ™ Pen Needle- K060007

Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

The BD AutoShield™ Duo Pen Needle is a safety pen needle that provides protection from accidental needle sticks, from both the patient end and non-patient (pen connection) end.

Currently, BD markets the BD AutoShield™ safety-engineered pen needles which shield the front, or patient end (needle tip) and have been associated with a lower incidence of needle stick injuries. To further reduce the risk of accidental needle stick injuries, BD developed the AutoShield™ Duo Pen Needle, which, in addition to the added safety shield on the non-patient (pen connection) end, includes a redesign of the safety shield to a clear safety shield that enables the user to better visualize the needle while inserting it into the skin.

Prior to injection, the user will attach the AutoShield™ Duo Pen Needle to the pen. As the user proceeds with inserting the needle into the skin at a 90° angle, the shield will retract. Once the pen is removed from the skin the inner shield will deploy and lock in place. A red indicator band will appear confirming the pen needle has been used. Once the pen needle is removed from the pen, the orange shield on the non-patient (pen connection) end will deploy and cover the needle.

The BD AutoShield™ Duo Pen Needles are offered in various gauge sizes (30G and 31G) and lengths (5mm and 8mm).

An injection molded outer cover is assembled over the patient end of the cannula. This needle assembly is sealed with a peel-away label to provide a sterility barrier and tamper evidence.

The assembly consists of a double-ended cannula that is assembled into an injection molded hub. The internal threads allow the safety pen needle to be screwed onto pen injectors. The patient and non-patient (pen connection) end of the cannula are lubricated for ease of injection and septum penetration.

The patient end of the device has a mechanism that allows the needle to be shielded and locked after use. Once shielded, a red indicator band becomes present indicating product has been used. These product features help reduce the occurrence of accidental needle stick injuries.

The non-patient (pen connection) end of the cannula is visible prior to attachment to the pen injector. Following removal of the device from the pen injector, the needle is shielded with a mechanism that is designed to reduce the occurrence of accidental needle stick injuries.

The BD AutoShield™ Duo Pen Needle is sterile (gamma irradiation sterilization), non-toxic, and non-pyrogenic. It is a disposable, single use device.

5. **Statement of Intended Use/Indications for Use:**

The BD AutoShield ™ Duo Pen Needle is intended for use with pen injector devices for the injection of drugs.

The product has two safety shields, which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connection-end). The locked shields help reduce the occurrence of needle sticks from both ends of the needle.

6. **Description of Safety and Substantial Equivalence:**

A Safety Activation Study and Simulated Use Study were performed to confirm the device's safety and efficacy.

The Safety Activation Study was performed to confirm that both safety shields performed as intended, utilizing both Professional Healthcare Users and Non-clinical Pen Users. Based on performance testing results, the BD AutoShield™ Duo Pen Needle is safe and effective when used as intended.

The Simulated Use Study was performed to Validate the "Instructions For Use" (IFU) utilizing both Professional Healthcare Users and Non-clinical Pen Users. As demonstrated in the study, the use of this product does not alter the injection technique or the functionality of the pen injector.

BD AutoShield™ Duo Pen Needles are similar to BD AutoShield™ Pen Needles in that both use the same operating procedures, incorporate the same basic design, are manufactured using similar materials, offer the same gauge and needle lengths, are sterilized using the same mode and have the same SAL of 10^{-6}.

BD's currently markets AutoShield™ Pen Needle has a safety shield on the patient end (only). The BD AutoShield™ Duo Pen Needle has a safety shield on both the patient end and non-patient (pen connection) end. The 'Indications For Use' have been revised to reflect the additional safety shield. Both safety pen needle products help protect against accidental needle sticks.

Based on the device features, materials, intended use and performance, BD AutoShield™ Duo Pen Needles were shown to be substantially equivalent to the commercially available predicate device BD AutoShield™ Pen Needle.

The following Table summarizes the validation/verification testing that was performed.

Performance Characteristic/Test Description	Test Performed	Results
Activation of the Sharps Injury Prevention Feature	Bench Test (BD Protocol) by Professional Healthcare Users and Non-clinical Pen Users.	Met the acceptable criteria per the FDA Guidance document *"Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features, August 9, 2005"*
Simulated Use Study Criteria per US FDA Regulations ICH Guidelines, ISO 14155-1:2003(E), and Good Clinical Practices (GCP)	Validation of Instructions for Use (IFU) by Professional Healthcare Users and Non-clinical Pen Users.	Simulated Use Study results confirmed that the BD AutoShield™ Duo is safe and effective when used as intended.
	Tubing diameters	Per ISO 11608-2, section 4.3.1 (tubing dimensions meet OD and ID requirement).
	Patency of lumen	Per ISO 11608-2, section 4.4 (stylet, having a diameter equivalent to 80% ±2% of lumen ID passes through freely).
	Needle points	Per ISO 11608-2, section 4.5 (visually sharp at 2.5X magnification, designed to minimize coring and fragmentation).
	Non-Type A Needle (length)	Per ISO 11608-2, section 4.3.3 (patient end within indicated length ± 1.25 mm)
	Cannula load test (No pre-conditioning)	Per ISO 11608-2, section 4.9 and 9. ISO 7864 (cannula holds force of 34N for 5 seconds).
	Cannula load test (with pre-conditioning)	Per ISO 11608-2, section 4.9 and 9. ISO 7864 (cannula holds force of 34N for 5 seconds).
	Lubrication	Per ISO 11608-2, section 4.7 (droplets of lubricant shall not be visible with unaided eye inside the needle under normal light conditions (72-135 lux).
	Compatibility Testing	Per ISO 11608-2, section 4.10 (connectivity (torque).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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Becton, Dickinson and Company
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JUL 27 2011

Re: K110703
Trade/Device Name: BD AutoShield™ Duo Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Needle, Hypodermic, Single Lumen
Regulatory Class: II
Product Code: FMI
Dated: July 7, 2011
Received: July 11, 2011

Dear Ms. Lacatena:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110703

Device Name: BD AutoShield™ Duo Pen Needle

Indications For Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZ

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110703